

Guidelines for the Diagnosis and Outpatient Management of Diabetic Peripheral Neuropathy

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Guidelines on the out-patient management of diabetic peripheral neuropathy have been developed from an international consensus meeting attended by diabetologists, neurologists, primary care physicians, podiatrists and diabetes specialist nurses. A copy of the full document follows this summary (Appendix 1). The document arose out of suggestions from Neurodiab, a subgroup of the European Association for the Study of Diabetes, that there was a need for guidelines developed by consensus, for the outpatient management of patients with diabetic neuropathy. An international consensus group was created, chaired by two of the authors. A pilot working party met in 1995, followed by a full working party of 39 experts, neurologists and diabetes physicians (Appendix 2). This compiled a draft guideline document which was circulated to a number of international bodies. After consultation with its members, the final guidelines were approved by Neurodiab (chairman F.A. Gries) towards the end of 1997. © 1998 John Wiley & Sons, Ltd.

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Definition

Diabetic peripheral neuropathy: the presence of symptoms and/or signs of peripheral nerve dysfunction in people with diabetes, after exclusion of other causes (Table 1).

Assessment as Part of the Annual Review of the Patient

Patient history: age, diabetes, physical factors, lifestyle, social circumstances, symptoms, other possible aetiological factors.

Examination should include:

- Inspection of both feet (Table 2): skin status, sweating, infection, ulceration, calluses/blistering, deformity, muscle wasting, arches; palpation for temperature, pulses, joint mobility; examine gait/shoes
- Vascular examination—foot pulses
- Other investigations, e.g. thyroid function, to exclude non-diabetic aetiologies
- Inspection for the presence or absence of characteristics of the 'at risk' foot (Figure 1).

Table 1. Stages of diabetic peripheral neuropathy

Stage of neuropathy	Characteristics
No neuropathy	No symptoms or signs
Clinical neuropathy	
Chronic painful	Burning, shooting, stabbing pains ± pins and needles; increased at night; absent sensation to several modalities; reduced/absent reflexes
Acute painful	Severe symptoms as above (hyperaesthesia common); may follow initiation of insulin in poorly controlled diabetes; signs minor or absent
Painless with complete/partial sensory loss	Numbness/deadness of feet or no symptoms; painless injury; reduced/absent sensation; reduced thermal sensitivity; absent reflexes
Late complications	Foot lesions; neuropathic deformity; non-traumatic amputation

1. Types of diabetic neuropathy: frequent, sensorimotor symmetrical neuropathy (mostly chronic, sensory loss or pain), autonomic neuropathy (history of impotence and possibly other autonomic abnormalities); rare, mononeuropathy (motor involvement, acute onset, may be painful), diabetic amyotrophy (weakness/wasting usually of proximal lower limb muscles).

2. Staging does not imply automatic progression to the next stage. The aim is to prevent, or at least delay, progression to the next stage.

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Table 2. Foot tests

Pin prick test	<ul style="list-style-type: none"> • Use a disposable instrument, e.g. a disposable pin
Light touch	<ul style="list-style-type: none"> • Ask 'Is it painful?' not 'Can you feel it?' • Use a consistent method, ideally a cotton wisp
Vibration test	<ul style="list-style-type: none"> • Use a 128 Hz tuning fork, initially on the big toe
Pressure perception	<ul style="list-style-type: none"> • Absence of sensation in the foot to a 10 g monofilament
Ankle reflex	<ul style="list-style-type: none"> • Compare the ankle reflex with the knee reflex

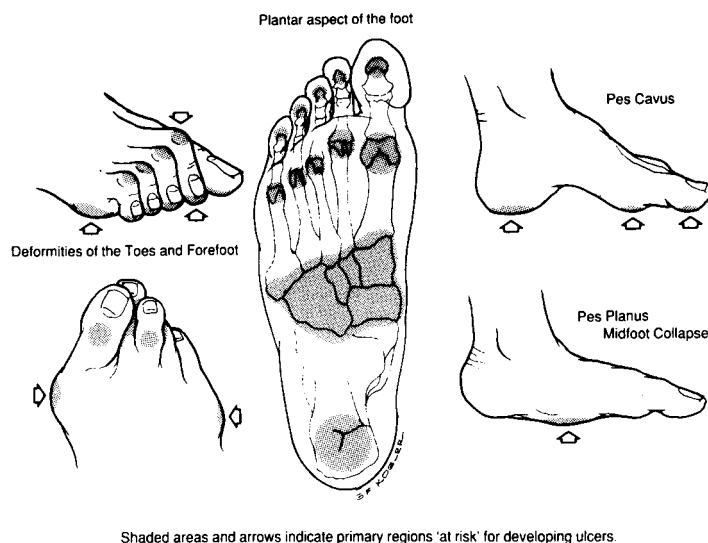


Figure 1. The 'at risk' diabetic foot (illustration by G. Kogler)

Management

Education of people with clinical neuropathy and referral of people with late complications to a diabetologist or neurologist are the key factors in the prevention of amputation (Table 3). Prompt referral (same day/next available day) of the person with the following lesions will usually prevent amputation: ulcer, blister, bleeding callus, cellulitis, acute ischaemia.

Appendix 1

International Guidelines on the Outpatient Management of Diabetic Peripheral Neuropathy

Developed from discussions at a meeting of a Pilot Working Party held in Brussels, Belgium, on 13 April 1995 and a meeting of a full Working Party held in London, UK, on 20–22 October 1995.

Introduction

Lack of awareness and inappropriate management of diabetic peripheral neuropathy leads to unnecessary morbidity and substantial healthcare costs. At least half of the foot ulcers, the

end stage of such neuropathy, should be preventable by appropriate management and patient education. However, lack of time and inadequate knowledge and information may lead, in many cases, to suboptimal management.

There is a clear need for a set of simple, practical, international guidelines to be used by primary care physicians (in many countries, 80–90 % of people with diabetes receive care from general practitioners) and by hospital physicians for the clinical assessment and management of neuropathy. The guidelines should be applicable in day-to-day practice and should use readily available methods.

The neuropathy study group (Neurodiab) of the European Association for the Study of Diabetes (EASD) has identified the need for three sets of guidelines for diabetic peripheral neuropathy. These will cover the following areas:

- studies of the epidemiology of peripheral and autonomic diabetic neuropathy (DN)
- conduct of clinical trials in DN
- management of diabetic peripheral neuropathy by practising clinicians.

The International Guidelines on the Outpatient Management of Diabetic Peripheral Neuropathy have been developed to fulfil the third need.

The purpose of this document is to provide clear, internationally acceptable guidelines on the clinical diagnosis and management of diabetic peripheral neuropathy in primary or hospital care, the widespread adoption of which would bring about earlier diagnosis, better management, and a reduction in the late sequelae of this complication of diabetes.

The guidelines provide recommendations on methods of assessment and management of diabetic peripheral neuropathy and patient education, all of which should form part of the annual review of people with diabetes. A simple staging system has been developed for diabetic peripheral neuropathy to provide a framework for risk assessment and decisions on treatment and referral of those with diabetes. The emphasis is on simplicity and practicality to facilitate maximal adoption.

It is intended that the guidelines should be used by physicians involved in the outpatient management of the person with diabetes. In addition, the guidelines emphasize the concept of a multidisciplinary diabetes footcare team and it is expected that the team members would use those sections that are applicable to their discipline. Clearly, there are variations in the epidemiology of diabetes, economic and cultural factors and healthcare personnel in different geographical regions; therefore, the guidelines should be adapted to meet local needs and conditions.

Peripheral Neuropathy in Diabetes

People with diabetes mellitus develop several types of peripheral neuropathy, including a distal sensory motor polyneuropathy, autonomic neuropathy, and mononeuropathy. The sensory motor polyneuropathy is the most common form of diabetic peripheral neuropathy and is the main focus of these guidelines. Estimates of its prevalence vary, although it is generally accepted that clinical diabetic peripheral neuropathy is found in approximately 30 % of people with diabetes. In the USA, the risk of foot ulceration, a late complication of neuropathy, has been estimated to be 3 % per patient per year. Neuropathy is also a major contributory factor in amputation. The incidence of amputation varies from country to country, owing to differences in the management of diabetes and diabetic foot disease. It is estimated, however, that 40 % of non-traumatic foot and leg amputations in adults are due to diabetes.

There is an urgent need for improvement of the clinical management of neuropathy in primary care. At least half of the amputations in people with diabetes are believed to be

Table 3. Management of the stages of neuropathy

Stage	Objectives	Key element	Referral
No clinical neuropathy	Education to reduce risk of progression; maintenance of near-normoglycaemia	Education; glycaemic control; annual assessment	As required
Clinical neuropathy	Management of symptoms; prevention of foot ulceration		
Acute/chronic painful		Stable glycaemic control; symptomatic treatment (simple analgesics or tricyclic drugs or carbamazepine). Consider referral of acute sensory neuropathy	Diabetologist/neurologist
Painless/loss of sensation		Education, especially footcare; glycaemic control according to needs	Appropriate member of foot care team
Other types of diabetic neuropathy		Early referral	Neurologist/diabetologist
Late complications	Prevention of new/recurrent lesions and amputation	Emergency referral if lesions present; otherwise referral within 4 weeks	Diabetologist/neurologist/chiropodist/podiatrist/diabetes specialist nurse/diabetic foot clinic if available

preventable, yet there are still reports of people presenting with foot ulcers in whom diabetes, let alone neuropathy, has not been diagnosed. Neuropathy also has a major impact on healthcare costs. In the USA it is estimated that the cost of the sequelae of neuropathy, foot ulcers, and amputations is equal to the entire cost of the remainder of diabetes management.

Guidance for the primary care physician is lacking. In addition, the physician has limited time available for consultation with the patient with diabetes. It is the objective of this document, therefore, to provide clear and simple guidelines for the diagnosis and management of neuropathy on an outpatient basis, in particular during the annual review of the patient. The emphasis is on simple diagnostic testing, using equipment that is readily available. Although much can be done in primary care to manage and educate people with diabetes, guidance is also given on when it is appropriate to refer the patient to a member of the multidisciplinary diabetes footcare team. The availability of resources will vary in different locations and it is possible that some reorganization or modification of referral procedures may be required to achieve optimal management.

Adoption of the guidelines should lead to improvements in the management of neuropathy and this should be documented. Systems should, therefore, be established to monitor the implementation of the recommended practices and to assess their impact, in terms of reduction of the incidence of foot ulceration and amputation, in people with diabetes.

Definitions

Diabetic peripheral neuropathy is the presence of symptoms and/or signs of peripheral nerve dysfunction in people with diabetes, after exclusion of other causes.

Stages of Neuropathy

A staging system has been developed for neuropathy to provide a framework for diagnosis and management. Staging does not

imply automatic progression to the next stage and the aim is to prevent, or at least delay, progression (Table A1).

Assessment

Clinical assessment of neuropathy should form part of the annual review of the person with diabetes. The objective is to detect the presence of clinical neuropathy. Risk factors for the development and progression of neuropathy and the development of neuropathic foot ulceration are shown in Table A2.

Patient History

Questions should be adjusted according to the age of the patient, type of diabetes and symptomatology, although in general the following areas should be covered:

- Age
- Diabetes: type; duration; therapy; level of glycaemic control; knowledge of diabetes and its complications
- Physical factors: inability to see well or reach the feet
- Lifestyle: smoking; alcohol intake; nutrition; employment; sport/leisure activities; footwear
- Social circumstances: socio-economic status; mobility; home circumstances; social support; access to care
- Symptoms

Symptomatology differs according to the stage and type of neuropathy (see above). Patients should be asked about the following:

- presence/absence of symptoms
- nature of symptoms, i.e. positive or negative symptomatology
- duration and progression of symptoms
- nocturnal exacerbation
- patients with chronic pain: ask if the pain is insidious, intermittent, bilateral, related/unrelated to treatment,

Table A1. The stages of neuropathy

Stage	Characteristics
Stages 0/1: no clinical neuropathy	<ul style="list-style-type: none"> No symptoms or signs
Stage 2: clinical neuropathy	
Chronic painful	<ul style="list-style-type: none"> Positive symptomatology (increasing at night): burning, shooting, stabbing pains \pm pins and needles Absent sensation to several modalities and reduced or absent reflexes
Acute painful	<ul style="list-style-type: none"> Less common Diabetes poorly controlled, weight loss Diffuse (trunk) Hyperaesthesia may occur May be associated with initiation of glycaemic therapy Minor sensory signs or even normal peripheral neurological examination
Painless with complete/partial sensory loss	<ul style="list-style-type: none"> No symptoms or numbness/deadness of feet; reduced thermal sensitivity; painless injury Signs of reduced or absent sensation with absent reflexes
Stage 3: late complications of clinical neuropathy	<ul style="list-style-type: none"> Foot lesions e.g. ulcers Neuropathic deformity e.g. Charcot joint Non-traumatic amputation

1. Subclinical neuropathy (Stage 1). This can only be diagnosed in special neurophysiological laboratories and such tests are not recommended for day-to-day clinical practice. Thus, Stage 1 cannot be differentiated clinically from Stage 0.

2. Diabetic amyotrophy. This is a predominantly motor disorder, usually encountered in elderly patients with undiagnosed or poorly controlled Type 2 diabetes. There is muscle weakness and wasting, mainly affecting the proximal lower limb muscles with a subacute onset. Sensory loss is slight, but pain, particularly at night, is common.

Table A2. Risk factors for development and progression of neuropathy and development of neuropathic foot ulceration

Risk factors for the development and progression of neuropathy	Risk factors for the development of neuropathic foot ulceration
<ul style="list-style-type: none"> Poor glycaemic control Undiscovered Type 2 diabetes Smoking High alcohol intake Low socio-economic status Renal failure 	<ul style="list-style-type: none"> Loss of pain sensation Undiscovered Type 2 diabetes Smoking High alcohol intake Low socio-economic status Patient lives alone lack of flexibility/suppleness Ill-fitting footwear Poor foot hygiene/footcare Denial of condition Lack of diabetes education History of previous ulceration or amputation Poor glycaemic control Peripheral vascular disease Decreased vibration sensitivity

– does it occur on walking or at rest; presence of foot ulcers in the past; presence of autonomic symptoms patients with acute pain: presence of neuropathic pain or contact hyperaesthesia

Other medical conditions/therapies which may be aetiological factors for neuropathy: vascular disease, HIV, vitamin B12 deficiency, hypothyroidism, weight loss, cancer, leprosy, syphilis, drug therapy, toxic exposure, paraproteinaemia.

Atypical features not usually related to diabetic neuropathy include rapid progression, foot drop, back or neck pain, weight loss (*per se*) and family history.

Examination of the Patient

Inspection of the Feet

The patient should be asked to remove shoes and socks on both feet. The feet should be inspected for the following:

- skin status: colour, thickness, dryness, cracking, trophic changes
- sweating
- infection (interdigital fungal infection)
- ulceration
- calluses/blistering
- deformity, e.g. Charcot joint or clawed toes
- muscle atrophy
- arches (standing/lying).

The feet should be palpated to assess temperature, foot pulses and joint mobility. The patient's gait and shoes should also be examined.

Neurological Examination

Four tests are recommended (see Table A3). All should be done bilaterally and the result should be a simple yes/no or normal/abnormal answer. For the first three, a proximal site should be compared with a distal site (vibration test—only if the result is abnormal). A simple temperature assessment may also be made by placing a cold tuning fork on the patient's legs.

To determine whether the patient has diabetic amyotrophy, look for proximal muscle wasting and weakness and loss of knee jerks, often with little sensory loss.

Vascular Examination

Systemic blood pressure and pulses (posterior tibial and dorsalis pedis) should be recorded.

Other Investigations

Appropriate investigations, e.g. thyroid function tests, serum B12, serum paraprotein, assessment of metabolic control should

Table A3. Neurological tests

Pin prick test	<ul style="list-style-type: none"> Use a disposable instrument, e.g. a disposable dressmaker's pin Do not use a hypodermic needle Ask 'Is it painful?' not 'Can you feel it?'
Light touch	<ul style="list-style-type: none"> Use a consistent method, ideally a cotton wisp
Vibration test	<ul style="list-style-type: none"> Use a 128 Hz tuning fork, initially on the big toe
Ankle reflex	<ul style="list-style-type: none"> Compare the ankle reflex with the knee reflex
Pressure perception	<ul style="list-style-type: none"> Absence of sensation in the foot to a 10 g monofilament may be used to assess the risk of foot ulceration

be considered for medical conditions, other than diabetes, which may be aetiological factors for the neuropathy. The need for such investigations will vary according to local circumstances. Possible aetiological factors are listed above. Other tests may be suggested as a result of the clinical examination.

The 'At Risk' Foot

The characteristics of the 'at risk' diabetic foot are shown in Figure 1. Attention should be paid to the absence/presence of these during examination of the patient.

Management

Education of people with Stage 2 neuropathy and referral of people with Stage 3 neuropathy are key factors in the prevention of amputation. For optimal care of people with neuropathy, a local multidisciplinary footcare team should be established. Although the structure of the team will vary according to local healthcare resourcing, as many as possible of the following should be included:

- diabetologist
- diabetes specialist nurse
- chiropodist
- podiatrist
- surgeon.

No Clinical Neuropathy (Stage 0/1)

Objective: education to reduce the risk of progression.

In Stage 0/1 the person does not have clinical neuropathy and, therefore, the emphasis is on education with respect to lifestyle, footcare, and metabolic control. At this stage there is no need for referral to a neurologist but referral to specialists in footcare, i.e. chiropodist, podiatrist or diabetes specialist nurse, may occasionally be indicated. A yearly foot examination has an important educational function. If, in future, specific therapies become available for the treatment of early neuropathy, the guidelines will require amendment to provide advice on the separate diagnosis and management of people with no neuropathy (Stage 0) and those with subclinical disease (Stage 1).

Clinical Neuropathy (Stage 2)

Objective: prevention of primary lesions and progression to late complications of clinical neuropathy (Stage 3).

Chronic Painful Neuropathy

For people whose daily lifestyle is not impaired by their neuropathy, there is no need to treat the symptoms. Attention should be given to maintenance of optimal glycaemic control, as assessed by glycated haemoglobin levels.

People who are disabled or whose quality of life is impaired should be referred to a diabetologist or neurologist with an interest in diabetes. In the interim, optimal glycaemic control should be maintained. Pain should be treated with tricyclic drugs (e.g. imipramine) as first-line therapy, starting with a low dose at night and increasing as necessary. If tricyclic drugs are contraindicated or ineffective, the person could be referred. New agents are available in some countries but these should

be considered only if their efficacy has been demonstrated in more than one controlled clinical trial.

Acute Painful Neuropathy

These patients should be referred to a diabetologist or neurologist. In the interim, optimal glycaemic control should be maintained. The pain should be treated with simple analgesics, progressing to NSAIDs or tricyclic drugs. Other stronger agents may occasionally be necessary. The person should then be managed in accordance with the specialist's advice.

Diabetic Amyotrophy

People with suspected diabetic amyotrophy should be referred either to a neurologist or a diabetologist for a further evaluation.

Painless Neuropathy with Complete/Partial Loss of Pain Sensation

Patient education, particularly in relation to the risks of progression, is important for this group. Maintenance of optimal glycaemic control is recommended. Specific foot management may be required, including advice on footcare (see below) and treatment of fungal infections.

Referral will depend upon whether it is possible to manage the person adequately in the primary care setting and upon the needs of the individual. It may be necessary to refer the person to a diabetologist or diabetes specialist nurse if there are problems with glycaemic control or other complications of diabetes. The patient may be referred to a neurologist if the picture is atypical or the neuropathy may have a cause other than diabetes. If the foot is at risk, e.g. because of deformity or the person's inability to reach his/her toes, the patient may be referred to a chiropodist or podiatrist for footcare, including the provision of special footwear.

Late Complications of Clinical Neuropathy (Stage 3)

Objective: prevention of new/recurrent lesions and amputation.

At this stage, the key management issue is onward referral and its urgency. Advice and counselling, which involves the care giver or partner, is also important (see Patient Education).

Emergency Referral

The person should be referred to the specialist diabetes footcare team immediately (same day or next available day) if he/she has any of the following:

- ulcer
- blister
- bleeding callus
- cellulitis
- acute ischaemia.

Prompt referral at this stage will usually prevent amputation.

Vascular problems may have contributed to ulceration but, if peripheral pulses are present, the primary process is neuropathy with possible secondary infection.

The possibility of osteomyelitis should be considered; differentiation of this condition from a Charcot joint is difficult and requires referral for further investigation.

Ideally, the person should be referred with his/her care giver or partner. The specialist team should be provided with notes on the person's social circumstances, as a basis for risk

assessment, and confirmation should be obtained that the patient has attended the consultation.

If the patient cannot be seen immediately, e.g. because of a national holiday, then treatment with a broad-spectrum oral antibiotic should be started. Drugs such as clindamycin or Augmentin (amoxycillin and clavulanic acid in combination) are useful agents.

Subacute Referral

People with a Stage 3 diagnosis but no ulcer should be referred to the specialist diabetes footcare team but with less urgency. They should attend an appointment within 4 weeks.

Patient Education

Education of people with diabetes should be started before clinical neuropathy is present (Stage 0) and should be customized to the individual's circumstances and ability to understand. The content of the education will change according to the stage of neuropathy; for example, while glycaemic control should be stressed throughout, the emphasis on footcare and footwear will increase in clinical neuropathy (Stage 2) and late complications of clinical disease (Stage 3). It is recommended that there should be separate programmes for people with Type 1 and Type 2 diabetes, as more extensive advice is likely to be required for the elderly Type 2 than for the young person with Type 1 diabetes.

Initially, it is important to assess the patient's level of knowledge about his/her condition and then to implement a measure of whether the educational messages have been understood. Care givers/partners should be involved throughout.

Who Should Provide Patient Education?

The providers of patient education will vary according to local circumstances and may include:

- primary care physician (primary health care team members in the UK)
- diabetes specialist nurse
- chiropodist/podiatrist
- patient support groups (e.g. through diabetes associations).

It is essential that these healthcare personnel have received adequate training on neuropathy and its management.

Patient education may be provided at structured primary health care clinics, diabetes education centres or meetings of support groups. It is also possible to introduce elements of education during examination of the patient. For example, vibration sensation in a normal area of skin may be compared with impaired sensation in the neuropathic foot.

What Methods Should Be Used?

The methods used will depend upon local circumstances, e.g. availability of equipment, such as video recorders, or patient literacy. Methods that involve personal interaction are preferred by patients. Four commonly used methods are:

- one-to-one personal training sessions
- video: ideally with opportunity for discussion
- literature/pamphlets; only validated material should be used, e.g. the EASD Survival Kit for older people with Type 2 diabetes
- group sessions: often very effective.

What Elements Should the Education Programme Contain?

Footcare and Footwear

Ongoing surveillance of the feet by the patient is important. The following points should be emphasized:

- change hosiery every day; check for thickened seams
- wear well-fitting comfortable shoes, with insoles as appropriate
- wear new shoes for brief periods (2–4 hours per day) until adaptation has occurred
- examine feet each night for lesions, red spots, breaks in the skin
- cut and file nails carefully, with help from chiropodist/podiatrist/trained carer if unable to see or reach feet

Short written guidelines about footcare may be provided, containing information about whom to contact if a particular circumstance arises.

Metabolic Control

At all stages, the importance of optimal metabolic control (glycaemia and lipids) should be stressed.

Blood Pressure

Control of blood pressure should be discussed, if necessary.

Lifestyle Modification

The following lifestyle changes should be discussed, as appropriate:

- weight control/dietary modification
- reduction in alcohol intake
- cessation of smoking
- exercise: appropriate for the individual; should not impair foot hygiene or aggravate the neuropathic foot. In certain people, running or even excessive walking may be inadvisable.

General Information about Diabetic Neuropathy

Patients should be informed about the natural history of diabetic neuropathy and risk factors for progression. They should be told about likely interventions for pain, impotence, etc. For people with chronic painful neuropathy, it should be explained why the pain is occurring, i.e. nerve damage, and that if it disappears it does not necessarily mean that the neuropathy has improved. If tricyclic drugs are prescribed, the patient should be told that pain relief may not occur for up to 3 weeks and that they should continue to take the tablets. Patients with acute painful neuropathy should be told that the pain will improve with time.

Patients with sensory loss must be made aware of the lack of sensation and hence the risks of injury to the foot.

The advice of a psychologist may help to deal with problems of denial of the condition, particularly in the later stages of neuropathy.

Summary of the Management of Neuropathy

Key elements for the management of each stage of neuropathy are shown in Table A4.

Acknowledgement

The consensus meetings were supported by an educational grant from F. Hoffmann La Roche, Ltd.

Table A4. Management of the stages of neuropathy

Stage	Key elements	Referral
No clinical neuropathy (Stage 0/1)	Education; glycaemic control ^a Annual assessment	Chiropodist/podiatrist/diabetes specialist nurse
Clinical neuropathy (Stage 2)		
Chronic painful	If disabled, treatment with tricyclic drugs; glycaemic control	Diabetologist/neurologist
Acute painful	Simple analgesics/tricyclic drugs/NSAIDs/opiates; glycaemic control	Diabetologist/neurologist
Painless/loss of sensation	Education, especially footcare; glycaemic control	Appropriate member of footcare team according to needs
Diabetic amyotrophy	Early referral	Neurologist/diabetologist
Late complications (Stage 3)	Emergency referral if lesions present; otherwise referral within 4 weeks	Diabetologist/neurologist/ chiropodist/podiatrist/ diabetes specialist nurse

^aIf, in future, specific therapies become available for the treatment of early neuropathy, the guidelines will require amendment to provide advice on the separate diagnosis and management of people with no neuropathy (Stage 0) and those with subclinical disease (Stage 1).

Appendix 2

List of Participants

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